UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF MISSISSIPPI

EASTERN DIVISION (HATTIESBURG)

DENNIS NELSON, et al., **PLAINTIFFS,** **v.** **C.R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC.,** **DEFENDANTS.**	**CIVIL ACTION** **NO.: 2:19-cv-00135-KS-MTP** **DISTRICT JUDGE STARRETT** **MAGISTRATE JUDGE PARKER**

PLAINTIFFS' RESPONSE TO DEFENDANT'S
MOTION FOR SUMMARY JUDGMENT

MAY IT PLEASE THE COURT:

NOW INTO COURT, through undersigned Counsel, come Dennis Nelson and Kathy Nelson ("Mr. Nelson" and "Mrs. Nelson", "Plaintiff", or "Plaintiffs"), who pursuant to Fed. R. Civ. P. 56 and Uniform Local Rule 7 respectfully submits this Response to C.R. Bard, Inc.'s and Bard Peripheral Vascular, Inc.'s (collectively "Defendants" or "Bard") Motion for Summary Judgment.

INTRODUCTION AND PROCEDURAL HISTORY

Mr. Nelson was implanted with a permanent Bard Recovery Inferior Vena Cava Filter (the "IVC" filter" or "Recovery filter") on May 16, 2005. At least six months beforehand, Bard knew that the Recovery filter fractured, migrated, tilted, and/or perforated patients' inferior vena cava[1] at rates significantly higher than competitor's IVC filters and Bard's own Simon Nitinol Filter ("SNF"), the device upon which the Recovery filter was predicated. Despite this knowledge, Bard did not warn implanting physicians—including Mr. Nelson's implanter Dr. Daniel DeVun—of these privately known significantly increased risks of serious injury and death. Years later, Mr. Nelson learned that multiple struts of his Recovery filter had fractured, tilted, and embedded into his inferior vena cava wall requiring three surgical procedures to remove most of the device and

[1] The vena cava the largest vein carrying deoxygenated blood back to the heart and lungs..

various fractured pieces. However, one piece remains in Mr. Nelson's lower right pulmonary lobe. Unfortunately, its extraction will require open chest surgery and surgical removal of part of his lung. For the reasons set forth herein, Plaintiffs ask the Court to deny Defendants' motion on all claims except manufacturing defect, which Plaintiffs hereby withdraw. Moreover, since Mrs. Nelson's claim for loss of consortium is derivative, dismissal of Mrs. Nelson's claim is premature.

I. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate when no genuine issues of material fact exist. See Fed. R. Civ. P. 56(a). As the party seeking summary judgment, Bard "bears the initial responsibility of informing the court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." Fed.R.Civ.P. 56; Zaffuto v. City of Hammond, 308 F.3d 485, 492 (5th Cir. 2002); Celotex Corp. v. Catrett, 477 U.S. 317, 322-23, 106 S.Ct. 2548, 91 L.Ed. 265 (1986). The evidence offered by the nonmoving party "is to be believed, and all justifiable inferences drawn in that party's favor because '[c]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are jury functions[.]" Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Summary judgment may be granted "when it can be shown that a trial would serve no useful purpose" on the issue. *Fontenot v. Upjohn Company*, 780 F.2d 1190, 1197 (5th Cir.1986).

ARGUMENT AND AUTHORITIES

Defendants' Motion for Summary Judgment seeks the dismissal of Plaintiff's causes of action for strict liability, negligence, negligent misrepresentation, breach of express warranty, breach of implied warranty, fraudulent misrepresentation, fraudulent concealment, Mississippi Consumer Protection Act Claim, along with Plaintiff's claim for punitive damages.

On September 18, 2017, this case was directly filed in the multi-district litigation ("MDL") as part of the In Re: Bard IVC Filters Products Liability Litigation MDL No. 2641 centralized in the District of Arizona. The MDL Court entered a series of case management orders ("CMOs") ordered the use of Short Form Complaints and other orders as a manner of efficiently managing thousands of cases for pre-trial proceedings.

> On or after **December 28, 2015**, any plaintiff whose case would be subject to transfer to MDL 2641 may file his or her case directly in this Court by using the Short Form Complaint. If such a case is filed in this Court without the use of the Short Form Complaint, Plaintiffs' Co-Lead Counsel shall promptly advise the filing party to file an amended complaint using the Short Form Complaint…
>
> Defendants are not required to file answers to Short Form or Amended Short Form Complaints. An Entry of Appearance shall constitute a denial of all allegations in the Short Form or Amended Short Form Complaints except as herein provided, and an assertion of all defenses included in the Master Responsive Pleading. By filing an Entry of Appearance in response to a Short Form Complaint, in lieu of an answer, Defendants do not waive any defenses, including jurisdictional and service defenses. Civil actions in this MDL were transferred to this Court by the Judicial Panel on Multidistrict Litigation for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. Upon completion of the pretrial proceedings related to a civil action as determined by this Court, the case shall be transferred pursuant to 28 U.S.C. § 1404(a) or § 1406(a) to the District Court identified in the Short Form Complaint, provided the parties choose not to waive *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998).

Case Management Order No. 4, December 17, 2015

Mr. Nelson, through his counsel, complied with the Court's orders and utilized the Short Form Complaint. Defendants similarly availed themselves of the MDL Court's orders regarding pleadings and did not respond specifically to Mr. Nelson's claims. On September 10, 2019, this case was transferred to this Court via 28 U.S.C. §1404(a). Plaintiff agrees that several of his claims are subsumed by the Mississippi Product Liability Act ("MPLA") yet complied with the pleading requirements of the MDL Court. Moreover, viewing the evidence presented in a light most favorable to Plaintiff, there is sufficient evidence to demonstrate a genuine issue of material fact as to the causes of action Plaintiff pursues under the MPLA, design defect and failure to warn, and as such, Defendants' Motion should be denied in its entirety.

A. Plaintiff Seeks Leave to Amend Complaint To Comport With The MPLA.

In diversity actions, the substantive law of the State of Mississippi controls. *Erie R.R. v. Tompkins*, 304 U.S. 64 (1938). In Mississippi, product liability claims are subject to the Mississippi Product Liability Act ("MPLA"). The Mississippi Supreme Court has set forth that "the MPLA provides the exclusive remedy for products-liability claims." *Elliott v. El Paso Corp*., 181 So.3d

263, 268 (Miss. 2015) (internal quotation mark omitted). The MPLA recognizes three categories of product defects: (1) design defects; (2) warnings/instruction defects, and (3) manufacturing defects. *See* Miss. Code Ann. § 11-1-63; *Hall v. Smith & Nephew, Inc*., 5:19-CV-13-DCB-MTP, (S.D. Miss. May 29, 2020). Plaintiff's strict liability claims related to design defect and failure to warn, as well as negligence, negligent misrepresentation, fraudulent misrepresentation, fraudulent concealment, expressed warranty, and implied warranty (Counts II – XIII) are based on the damages caused by product defects and subsumed by the MPLA. *Little v. Smith & Nephew, Inc*., 2015 WL 3651769 (N.D. Miss. June 11, 2015). Should the Court desire the MDL-approved pleading converted to include a complaint that comports with the MPLA, Plaintiff requests leave to amend. *Elliot v. El Paso Corp.,* 181 So. 3d 263, 268 (Miss. 2015).

B. Plaintiff Seeks Leave To Amend Complaint To Comply With The Mississippi Consumer Protection Act Claim.

Plaintiff requests leave to amend his complaint to comply with the Mississippi Consumer Protection Act (Count XIV) and make a "reasonable attempt to resolve any claim through an informal dispute settlement program approved by the Attorney General" as is required under the Mississippi Consumer Protection Act Claim and Mississippi law. *Joan Cravens, Inc. v. Deas Constr. Inc.,* 1:15-CV-385-KS-MTP, (S.D. Miss. June 23, 2016); Miss. Code. Ann. § 75-24-15(2).

C. Plaintiff Withdraws His Causes Of Action For Manufacturing Defect.

Plaintiff has determined that he will no longer pursue his claim based on Manufacturing Defect (Count I) and will not defend such claims on either a strict liability or negligence theory of culpability.

D. Plaintiff Has Provided Sufficient Evidence To Raise A Genuine Issue Of Material Fact Regarding Causation.

Drs. Hurst's testimony is sufficient to raise a genuine issue of material fact, evidencing that, at the time of Mr. Nelson's implantation, the risks associated with the Recovery filter exceeded the alleged benefits to the plaintiff who needed safe and effective protection against DVT and PE. Mr. Nelson's Recovery filter failed to perform as a reasonable physician and/or patient would expect. See Plaintiffs' Statement of Material Facts as to Genuine Issues for Trial ("SOF"),

cited above, SOF 70-96. The following failures are documented: In a cascade of events that is typical of the Bard Recovery filter, the device caudally migrated, the device fractured, components embolized away from the filter to the pulmonary arteries, components were embedded at the filter level, and the components (legs and arms) of the device penetrated the IVC and interacted with or penetrated surrounding organs and structures. SOF 44-53; 64-69. There were multiple interactions with and penetration of legs and arms of the spine/L4 vertebral body, which likely resulted in chronic back pain in the plaintiff. SOF 64-69. There was focal interaction of a leg with the aorta. SOF 45. There was penetration of the right psoas muscle which likely resulted in chronic back pain in the plaintiff. SOF 67. The symptomatic penetrations and the fractures described below led to a complex IVC filter retrieval procedure and two attempts at removal of the embolized, fractured components. SOF 44-69.

The device fractured in multiple locations. One fractured arm of the device embolized to the right middle lobe medial segment pulmonary artery and was unable to be removed SOF 44-53. Subsequent attempts to remove the arm led to thrombosis of the right middle lobe medial segment pulmonary artery. SOF 44-53. This retained foreign body places the plaintiff at significant risk of future vessel damage, pneumothorax, hemorrhage, or infection. Any and all of these complications could cause additional morbidity, or be life threatening. SOF 59. If the patient experiences complications related to the retained fragment, treatment would require surgical removal, pulmonary lobectomy, and thoracotomy with the risk of complications associated with those procedures. SOF 54-63. The patient will require lifelong surveillance to monitor for further migration of the fragment with yearly chest radiographs and possibly chest CT if there are symptoms or concern for migration. SOF 130, 136.

One fractured arm of the device embolized to the right lower lobe anterior segment pulmonary artery and was removed percutaneously on 12/18/19. SOF 52. Because the fractured strut is retained in Mr. Nelson's pulmonary artery he is at risk of: Migration through the wall of the artery, laceration to the artery leading to bleeding, cardiovascular collapse or coughing up blood, inflammatory response similar to an allergic reaction in that portion of the lung, reduction

in lung function, and clot propagation leading the existing clot to advance into additional branches of Mr. Nelson's pulmonary artery. SOF 59.

Physicians and patients expect Bard to produce a safe, and effective device that accomplishes the intended purpose with the lowest possible risk to the patient. SOF 70-96. The Bard Recovery IFU was inadequate for use by physicians in medical decision making and consent of the patient. SOF 89-96. The IFU describes possible risks following IVC filter placement, without providing clear information on the likelihood of those risks or the potential severity of new complications such as, for example, penetration of the IVC and adjacent structures/organs. SOF 89-96. The IFU provides no clear recommendations for imaging follow-up of the device. SOF 113. The IFU provides no timeline for removal of the device, claiming that the device is safe and appropriate for both temporary and permanent use. SOF 113. The IFU provides insufficient warning of the incidence and seriousness of the cascade of events of tilt, migration, fracture, and especially penetration of the IVC and adjacent structures and organs that was characteristic of these devices and occurred with a higher frequency and more serious complications than the prior permanent SNF device and other permanent filters available at the time. SOF 3, 15, 17, 35, 70-96; 111-122; 123-126. During the time that the Recovery filter was available, Bard elected not to warn physicians and patients who had implanted devices, including the Mr. Nelson and his implanting physician of the incidence and seriousness of the cascade of events of tilt, migration, fracture, and penetration of the IVC and adjacent organs/structures that are characteristic of the device that occurred with a higher frequency and with more serious complications than the prior permanent SNF device and other filters. SOF 70-96; 111-122; 123-126. There were multiple safety signals with the Recovery filter. SOF 7,13,15-16, 19-20, 23-25, 29-30, 32, 35These signals came from MAUDE adverse event reports and from Bard's own internal risk analyses and documents. SOF 30, 32. Bard failed to notify the operating physicians and the implanted patients of the much higher complications rates of fracture, embolization of featured components, penetration, migration, including the known risk of death associated with the Recover filter and in comparison, to the original predicate device, the Simon National Filter, and competitor filters. SOF 19-32. Bard failed

to recommend and continues to not offer guidance on monitoring of the Recovery filter and failed to recommend timely removal of the device despite knowing the above risk of morbidity and mortality from deterioration of the device. SOF 27, 84, 113, 118, 121.

Dr. Muehrcke's report and testimony is sufficient to raise a genuine issue of material fact, evidencing that: Mr. Nelson's Recovery IVC filter failed by perforation, fracture, tilting, embolization of two fragments to his right pulmonary artery and one locally. SOF 100-107; SOF 119, 138. His Bard IVC filter was demonstrated to clear interact with the L4 vertebral body and right psoas muscle; causing osteophyte formation and, more likely than not; back pain. SOF 136. There is no evidence the filter ever prevented a pulmonary embolism in Mr. Nelson. Furthermore, Dr. Muehrcke testified about articles showing that IVC filters have no lifesaving benefits but increase risks of complications including deep venous thrombosis. SOF 139. Therefore, the risk of the filter outweighed any benefit in Mr. Nelson specifically. Indeed, the IVC filter strut which migrated to the lungs actually cause a clot in the lungs; the very thing it was to prevent. The retained pulmonary fragment is a threat to Mr. Nelson potential future, as discussed by Marshall Walker, M.D., Plaintiff's treating physician and interventional radiologist. *See* SOF 59. Dr. Walker significantly agreed to a reasonable degree of medical probability that Dennis Nelson is at risk to experience complications that will remain for the rest of his life. SOF 59-63.

Mr. Nelson's future potential damages from the retained fragment include bleeding, infection, pain, and death. SOF 136. Mr. Nelson suffer anxiety from his retained IVC filter fragment. Mr. Nelson will therefore require lifelong CT scan surveillance of the abdomen and pelvis and counseling. SOF 136. He is also at risk for an emergency lobectomy. SOF 136. He will always be at risk for further problems for the rest of his life if the pulmonary filter fragment remains. Implanting and referring physicians (customers) were never adequately and appropriately warned of the dangers of the Bard Recovery filter. SOF 84, 85, 86, 87, 88, 89, 90, 91, 92, 112, 113, 115, 117, 118.

Bard did not instruct physicians to remove the filters after they were no longer needed to reduce any risk to implanted patients. SOF 113. Nor did it tell implanting physicians to follow

patients for complications Bard which was aware were occurring given their internal documents. SOF 39, 82-96. Bard failed to notify the operating physicians and the implanted patients of the much higher complication rates associated with the Recovery filter in comparison to the original predicate device, the Simon Nitinol Filter, and competitor filters. SOF 114. Bard did send out a Dear Colleague letter five months after learning their filter had a death rate 500% greater than all other IVC filters on the market.

The Bard Recovery IFU was inadequate for use by physicians in medical decision making and consent of the patient. SOF 85, 89-93. The IFU describes a myriad of possible risks following IVC filter placement, listing every possible risk known to physicians without providing clear information on the likelihood of those risks or the potential seriousness of new complications such as fragment embolization. SOF 83-93. The IFU lists a "laundry list" of so many potential complications or adverse events, it dilutes any important warning that could be obtained from the document. SOF 92

The IFU provides insufficient warning of the incidence and seriousness of the higher frequency and more serious complications than the predicate SNF device and other permanent filters available at the time. SOF 15-17, 19, 27, 30-35. There is little evidence to show that inferior vena cava filters save patients from embolism long-term. SOF 139. Yet there is significant evidence that patients who receive IVC filters suffer more complications from deep venous thromboses and filter-related complications than patients who do not have IVC filter implanted. SOF 139. Bard marketed and sold these devices despite the lack of clinical evidence of efficacy with their IVC filters. SOF 14, 16(b)-(c). It never tested them to ensure they were beneficial to patients long term, with the longest implant in the Asch study at 134 days. SOF 5-8. Instead, Bard allowed them to be implanted with little to no clinical evidence that they work. SOF 5-8, 15-17, 19, 27, 30-35, 81, 139.

Plaintiff has provided sufficient evidence that raise more than a reasonable inference that Mr. Nelson's injuries resulted from the Recovery filter. Bard did not meet the expectations of physicians, including those who implanted the filter in Mr. Nelson regarding the information Bard

should have provided. SOF 107.

Moreover, Plaintiff relies not only on Drs. Hurst's and Muehrcke's reports and testimony to establish causation—their reports and testimony that the fracture and embedment of Mr. Nelson's Recovery filter caused his injuries goes hand in hand with the MDL reports of Robert M. McMeeking, who has offered reports and testified as to the ways in which the Recovery filter's design was defective such that it carries a high risk of perforation, fracture, and tilting. SOF 107-110. It is irrelevant that Drs. Hurst and Merce, an interventional radiologist and cardiothoracic surgeon, did not offer an opinion regarding design defect— Dr. McMeeking, has presented thorough expert analysis demonstrating that the Recovery filter is defective in its design and that such design defect causes perforation, fracture, tilting. SOF 106-110;. Drs. Hurst and Muehrcke have opined that the Recovery filter caused Mr. Nelson's injuries by perforation, fracture, tilting, embolization of two fragments, and one to his pulmonary artery. Dr. DeVun also testified that had he been given the information regarding the Recovery's risk profile as to comparative failure rates found in the December 17, 2004 HHE, he would have discontinued use of the Recovery filters in his patients and would not have implanted one in Mr. Nelson. SOF 87-90. It is up to the jury to decide what weight to place on the expert opinions of Drs. McMeeking, and Hurst and Muehrcke; each expert has provided sufficient evidence to allow all a reasonable jury to find that the Recovery filter proximately caused Mr. Nelson's injuries. As such, Bard's Motion for Summary Judgment should be denied.

E. Plaintiff Has Provided Sufficient Evidence to Raise a Genuine Issue of Material Fact Regarding Failure to Warn.

Plaintiff filed a Motion for Partial Summary Judgement on March 12, 2021 with supporting documentation, testimony and evidence. For all the reasons set forth in Plaintiff's Motion incorporated as though fully set forth herein, and abbreviated below[2], Plaintiff has provided

[2] For a defendant to invoke the learned intermediary doctrine as a defense from liability, the manufacturer must provide adequate warnings to the physician. *Windham v. Wyeth Laboratories, Inc*. 786 F.Supp. 607, 611 (S.D. Miss. 1992) (citing *Thomas v. Hoffman-La Roche, Inc*., 731 F.Supp. 224, 228-229 (N.D. Miss 1989)). Only if the warning is adequate does the learned intermediary doctrine allow a defendant to be

sufficient evidence to raise a reasonable inference prove that Bard's inadequate warning proximately caused Plaintiff's injury: (1) the Recovery filter was defective because it failed to contain adequate warnings or instructions; (2) the defective condition rendered the product unreasonably dangerous to Plaintiff; and (3) the defective and unreasonably dangerous condition of the Recovery filter proximately caused Plaintiff's damages. Miss. Code Ann. § 11-1-63(a)(i)(2),

In addition, Plaintiff provides support from expert Dr. Hurst; he testified that interventional radiologists "expect Bard to provide product warnings that clearly identify the dangerous aspects of the product. These warnings must be adequately: clear, accurate, consistent, convey the likelihood, frequency, and severity of the risks involved with using the device." SOF 100, 101, 102, 103, 112, 113, 117. Further, a physician expects Bard to have a reasonable program of

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discharged from a duty to warn of a product's dangerous propensities. *Miss Valley Silica Co., Inc. v. Eastman*, 92 So.3d 666, 672 (Miss. 2012).

An adequate product warning "is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product." Miss.Code Ann. § 11–1–63(c)(ii); Johnson, 895 So.2d at 166. The mere mention of possible injury or failure mode, is not necessarily adequate. *Stahl v. Novartis Pharrns. Corp*. 283 F.3d 254, 266-67 (5th Cir. 2002). If a warning is deemed inadequate, the Plaintiff must show that an adequate warning would have altered the learned intermediary's conduct. *Wyeth Labs, Inc., v. Fortenberry*, 530 So. 2d 688, 691 (Miss. 1988). The adequacy of the warning provided must be "viewed from the context of the possible effect it may have had on the learned intermediary's conduct." *Windham*, 786 F.Supp at 612.

As part of the proximate cause inquiry, the Mississippi Supreme Court requires plaintiffs to prove that an alternative warning would have conveyed the information necessary for the victim to avoid the accident. *Williams v. Manitowoc Cranes, L.L.C*., 898 F.3d 607, 618 (5th Cir. 2018) (citing *Windham v. Wyeth Labs., Inc*., 786 F.Supp. 607, 612 (S.D. Miss. 1992). Essentially, if a further warning would have altered the physician's conduct, then the failure to warn would be the proximate cause of the plaintiff's injuries. *Windham*, 786 F.Supp. at 612. As such, Plaintiff must establish both of the following elements: (a) an adequate warning would have prevented the attending physician from implanting the device, and (b) the injury would not have occurred if the device had not been implanted. *Thomas,* 949 F.2d at 814-18.

A warning may be inadequate when a manufacturer knows its product carries a higher risk of injury than its competitor's similar product and does not share that information with physicians. *In re Bard IVC Filters Product Liability Litigation*, 969 F.3d 1067, 1076 (9th Cir. 2020) (affirming district court denial of motion for summary judgment and judgment as a matter of law as to failure to warn verdict against Bard related to IVC filter using Recovery filter as its predicate device). If a genuine issue of material fact exists when a physician's testimony indicates his conduct would have changed had he been informed of significant risks associated with a product, conversely, none exists when a physician testifies he would not have used the product had the manufacturer provided information that would have made him refrain from using the product. *Ebel v. Eli Lilly & Co.*, 321 Fed. Appx. 350, 357 (5th Cir. 2009). Moreover, when a doctor testifies he would have changed his conduct had he been accurately informed of the risks associated with a particular product, proximate cause of the injury exists. *Ebel v. Eli Lilly & Co*., 321 Fed. Appx. at 372–73.

surveillance for unexpected outcomes or complications and warn physicians of these complications when they arise. *Id.* In the remand order, the Honorable David Campbell held that interventional radiologists should not be precluded from offering expert testimony regarding the disclosures reasonable implanting physicians expect to receive from the manufacturers of IVC filters, because such testimony is "well within their expertise and experience." *See* Bard MDL Remand Order regarding Bard Motions to Exclude Expert Opinions, at 6–9, (Doc. 4).

Prior to Mr. Nelson's implantation, Bard was aware of the following: (1) the Recovery had substantially higher reported failure rates when compared to its predicate, the SNF; (2) that Bard had an obligation to warn implanting physicians of these higher failure rates because this risk was not obvious to the user; and, (3) Bard withheld this information, failing to include any mention of the Recovery filter's comparatively higher rates of failure and complications in the product's IFU or other informational material. If Bard had disclosed this information, Dr. Hurst opined that no reasonable physician would have placed the Recovery filter in Mr. Nelson. SOF 112, 113. This opinion is supported by the testimony of Mr. Nelson's implanting physician, Daniel DeVun, M.D., SOF 78-88. Bard did not adequately warn physicians, including Dr. DeVun, of important safety risks, comparative risks, and issues associated with its Recovery filter of which it was aware, at the time of implantation of the filter and ongoing to the present. SOF 78-88. That is, an adequate safety and comparative risk warning would have altered Dr. DeVun's conduct, thus the failure to warn is the proximate cause of Mr. Nelson's injuries. *Windham,* 786 F.Supp. at 611-612. *See also*, *In re Bard IVC Filters Product Liability Litigation*, 969 F.3d at 1076. (knowing that its product carries a higher risk of injury than its competitor's similar product a manufacturer fails to adequately warn when it does not share that information with physicians).

Dr. DeVun further testified that the IFU materials should include Bard's own internal data and knowledge concerning complication rates of the Recovery filter. SOF 86. Because the higher rates of reported adverse events, and in particular, events of fracture, were not included in the Recovery IFU or otherwise disclosed by Bard to physicians, including Mr. Nelson's implanting physician Dr. DeVun, it is irrelevant that Dr. DeVun signed a consent form attesting to having

explained the relevant risks to Mr. Nelson prior to implantation surgery. Dr. DeVun could only warn about risks of which he was aware. SOF 89-90.

Plaintiff has provided evidence that Dr. DeVun was not aware of the Recovery's comparatively higher risks as compared to other filters, and that, like any reasonable physician, he would not have chosen the Recovery filter for Mr. Nelson had Bard disclosed this information. Plaintiff has therefore shown sufficient evidence to raise a general issue of material fact that the Recovery filter "failed to contain adequate warnings," the inadequate warnings "rendered the product unreasonably dangerous to the user or consumer," and the inadequate warning "proximately caused the damages for which recovery is sought." *See* Miss.Code Ann. § 11–1–63(a)(i)–(iii) (Rev.2004); *3M Co. v. Johnson,* 895 So.2d 51, 166 (Miss. 2005). Bard's Motion for Summary Judgment should be denied.

F. Plaintiff Has Provided Sufficient Evidence to Raise a Genuine Issue of Material Fact Regarding Design Defect.

Under the Mississippi Law, Plaintiff has provided evidence that: (1) the Recovery filter was designed in a defective manner; (2) a defective condition rendered the Recovery filter unreasonably dangerous; (3) the defective and unreasonably dangerous condition of the Recovery filter proximately caused Plaintiff's damages; and (4) there existed a feasible alternative design that would to a reasonable probability have prevented the harm without impairing the utility, usefulness, practicality, or desirability of the Recovery filter. Miss. Code Ann. § 11-1-63(a)(i) -(f)(i)-(ii); *see also Brown v. Ford Motor Co.,* 121 F. Supp. 3d 606, 611 (S.D. Miss. 2015).

Defendants cite no authority that would indicate only case-specific experts may provide evidence regarding the filter's defective design, and in fact, if this was the situation, the entire purpose of the MDL—to efficiently discover fact issues shared in common between similar plaintiffs injured by the same product—would be defeated. Because Drs. Hurst and Muehrcke do not offer opinions regarding design defect, it does not defeat Plaintiff's causes of action. Plaintiff has designated general liability experts in this case, adopting the reports of Drs. Robert McMeeking, Robert Ritchie, and others. Plaintiff has provided Defendants with sufficient

evidence to prove the existence of a design defect in the Recovery filter that caused Mr. Nelson's injuries.

1. Plaintiff has provided sufficient evidence of design defect.

Plaintiff has provided sufficient evidence, including expert testimony, concerning the Recovery filter's defective design and reasonable alternative designs, as well as evidence from Bard's own data and documents concerning Bard's knowledge that the Recovery's design was defective. SOF 4, 8, 18, 20, 131-135.

Plaintiff's general liability expert Dr. Robert M. McMeeking, a structural and mechanical engineer, concluded that Bard filters, including the Recovery filter, was unsafe for implant into the body. *See* SOF 109, 123, 124. Dr. McMeeking's conclusions are based on his knowledge, education, experience, the examination of Bard design and qualification documentation regarding Bard's design, analysis, and testing of Bard IVC filters and his own mathematical analyses. SOF 109, 1001.

Dr. McMeeking has determined that the Recovery filter was prone to numerous failure mechanisms that were not appropriately analyzed, leading to erroneous conclusions about the risk of their occurrence; that the filter was not adequately analyzed or tested in appropriate laboratory experiments to accurately quantify the risk of tilting, migration, perforation and fracture; that the level of analysis and testing conducted by Bard was insufficient and below engineering standards; and that the analysis and testing that was undertaken by Bard did not test for worse case conditions. SOF 109, 1001.

Dr. McMeeking also provided extensive testimony about design defects of the Recovery filter and Bard's failure to adequately test in accordance with standards. SOF 109, 123, 124. Plaintiff has therefore provided more than sufficient evidence to create a genuine issue of material fact as to whether the Recovery Filter implanted into Mr. Nelson's was unreasonably dangerous as designed. Contrary to Defendants' conclusory assertion that Plaintiff presented no evidence that the fractured struts are the proximate cause of her injuries, Plaintiff's experts have specifically opined on the question of causation. Dr. McMeeking's testimony demonstrates that perforation of

the IVC wall, fracture, tilt, migration, and other mechanical failures result from the unreasonably dangerous design of the Recovery filter. SOF 109, 110. Dr. Walker testimony discussed *supra* demonstrates that the fractured struts of the Recovery filter were a contributing factor to Mr. Nelson's injuries would not have occurred but for the presence of the Recovery filter. SOF 44-47, 50-63. Together, this is sufficient evidence to create a genuine issue of material fact as to whether the Recovery filter's defective and unreasonably dangerous design cause Plaintiff's injuries. As such, Defendant's Motion for Summary Judgment should be denied.

2. Plaintiff has produced evidence of a feasible design alternative available at the time of sale.

Plaintiff has provided more than sufficient evidence that a feasible design alternative existed and to a reasonable probability would have prevented the harm to Plaintiff without impairing the utility, usefulness, practicality or desirability of the Recovery filter. *See* Miss. Code Ann. § 11-1-63 (f)(ii).

Plaintiff's experts, along with Bard's own internal documents, provide evidence to create a genuine issue of material and demonstrate that a feasible design alternative available at the time of sale. SOF 3, 15-20, 24-28, 30-32, 34-35. The most obvious evidence that the Recovery filter is defectively designed is that other IVC filter designs exist that are clearly safer. SOF 3, 15-20, 24-28, 30-32, 33, 35. Plaintiff has presented evidence that Bard's own SNF, as well as other IVC filters on the market at the time of the Recovery filters' sale, had lower rates of fracture, migration, and perforation than the Recovery filter.[3] Despite Defendants' argument to the contrary, the Recovery filter was designed to be a permanent filter, and was submitted to the FDA for clearance as a permanent device. SOF 5. Here, the implanting physician, Dr. DeVun, understood that the

[3] In *Hyde*, the MDL Court considered and rejected Bard's attempt to draw illusory factual distinctions between permanent and retrievable filters when the filter in question – here, the Recovery – had been marketed to be both. After noting that the plaintiff received a permanent filter, and that the complaint alleged that retrievable filters were not designed to be permanent, the Court held, "The evidence in this case suggests, however, that the G2 X and Eclipse filters were designed to be permanent filters (like the Recovery Filter), as was the SNF, and that Ms. Hyde's filter would have remained in place if it had not fractured. Whether the retrievability of the G2X and Eclipse made them sufficiently unlike the SNF to disqualify the SNF as a reasonable alternative design is a question for the jury to decide." ECF No. 12805, at 6.

Recovery filter was an "optional" filter, and testified that he expected it to behave as a permanent filter; that is, remain in place for the duration of a patient's life, and whether the filter was optional or permanent, it would have the same safety profile. SOF 37. Indeed, in Mr. Nelson's case, the filter did remain implanted as a permanent filter, whether the SNF, as a permanent filter, is a reasonable alternative design remains an issue of fact. Mr. Nelson's experience with the Recovery directly implicates this fact question. Bard's own Corporate Clinical Affairs, David Ciavarella, M.D. knew that the Recovery filter had fracture, perforation, migration, and embolization rates that were 4.6., 4.4, 4.1 and 5.3 times higher, respectively, than for the SNF. SOF 78-81.

Plaintiff's expert Dr. Hurst testified that interventional radiologists "expect that, when Bard has marketed and sold an IVC filter as being a "permanent" filter, even with the additional benefit of potential retrieval, Bard has adequately and appropriately designed and tested the filter to be safe and effective for implantation as a permanent device. (SOF 113) Further, a physician expects the filter will have the same risk profile (in terms of type, likelihood, frequency, and severity) as other permanent IVC filters in the absence of some warning or explanation that the risk profile for the new device is actually different. *Id.* Based on review of internal documents such as the Crisis Communication Plan and others, Dr. DeVun testified he would have wanted to know Bard was developing a plan to address problems with the Recovery which included a redesign and would not have used the Recovery filter. SOF 70-77.

Moreover, Dr. Hurst testified that the SNF, a permanent-placement-only filter, would *not* have impaired the utility, usefulness, practicality, or desirability of the Recovery, an optional or retrievable filter; testified "[i]t is my opinion within reasonable medical and scientific certainty that if the implanting physician determined that the plaintiff needed a permanent filter, the Simon Nitinol filter, which was on the market at the time of the filter implantation, was a safer alternative filter for the plaintiff because it would have significantly reduced the risk of the cascade of events of tilt, migration, and symptomatic penetration of the IVC and adjacent organs/structures he experienced without impairing utility of the device to patients." *Id*. Plaintiffs' engineering expert also testified as to design flaws and alternative design. SOF 108-110; 124.

3. Comment k does not bar design defect claims.

Defendants argue that under Comment k of the Restatement (Second) of Torts § 402A, manufacturers of IVC filters cannot be held liable because all filters (like all medical devices) have risks and all therefore are "unavoidably unsafe." In other words, Defendants are asking this Court to hold that categorically, all medical devices, including all IVC filters, have blanket immunity by virtue of Comment k. While some Mississippi courts have applied Comment k to certain cases involving prescription drugs, such application is limited to prescription drugs only and a "case-by-case" basis. *Bennett v. Madakasira*, 821 So. 2d 794, 809 (Miss. 2002). No Mississippi courts have ever applied Comment k to a medical device case.

For Comment k to apply in prescription product cases and in accordance with the cases Bard cites for support, it must show that the design of the Recovery filter was as safe as the best available testing and research permitted, and there was no feasible alternative design which accomplished the product's purpose with a lesser risk. *Adams v. G.D. Searle & Co*., 576 So. 2d 728, 732–33 (Fla. Dist. Ct. App. 1991) ("Thus, a product which is as safe as current testing and research permits should be protected. The reverse is also true; a product which is not as safe as current technology can make it should not be protected."); *West v. Searle & Co*., 305 Ark. 33, 40–41, 806 S.W.2d 608, 612 (Ark. 1991) (comment (k) only applies when there is no feasible design that accomplishes the product's purpose with lesser risk); *Bryant v. Hoffmann-La Roche, Inc*., 262 Ga. App. 401, 404, 585 S.E.2d 723, 727 (Ga. 2003).

Bard has failed to demonstrate that the Recovery filter is "unavoidably unsafe" as a matter of law. *Ebert v. C. R. Bard, Inc.,* 459 F. Supp. 3d 637, 653 (E.D. Pa. 2020). First, regardless of whether the Recovery filter is incapable of being made safe, there is no concrete evidence that it is actually effective as a prophylactic for pulmonary embolism, much less that there is a high degree of social need for the Recovery (or any other) IVC filter. SOF 139. Additionally, there exist several alternative designs for IVC filters, one of which is the predicate to the Recovery – Bard's Simon Nitinol Filter. *See Miller v. Stryker* Instr., 2012 WL 1718825 (D. Ariz. Mar. 29, 2012) (holding comment k did not apply when the FDA found that the device was substantially

similar to a predicate device); *Larsen v. Pacesetter Sys., Inc.*, 74 Haw. 1, 24–25, 837 P.2d 1273, 1286 (1992) (holding comment k did not apply to a pacemaker because "there were many different types of pacemakers available on the market, all of which were designed to perform the same function" as defendant's product). There were other filters available at the time of Mr. Nelson's implant, including filters manufactured by Bard, the Simon Nitinol Filter, that accomplished the same or similar goals as the Recovery filter, but had lower risks of fracture, migration, perforation, and death. See SOF 17, 19, 22, 25, 27, 29-34, 113, 125, 126. Bard cannot avail itself of Comment k in this instance, and Defendants' Motion for Summary Judgment should be denied as to this argument.

G. Plaintiff Has Provided Sufficient Evidence to Support her Claim for Punitive Damages.

An award of punitive damages requires proof by clear and convincing evidence that the defendant acted with actual malice, gross negligence which evidences a willful, wanton or reckless disregard for the safety of others, or committed actual fraud." Miss.Code Ann. § 11–1–65(1)(a). In deciding whether to submit the issue of punitive damages to a jury, the trial court looks at the record and the totality of the circumstances to determine if a reasonable, hypothetical juror could find either malice or gross neglect/reckless disregard. *Johnson & Johnson, Inc. v. Fortenberry*, 234 So. 3d 381, 407 (Miss. 2017) (citing *Bradfield v. Schwartz*, 936 So.2d 931, 936 (¶ 15) (Miss. 2006)). There is no precise definition of gross negligence, but one of the approximate definitions may be thus expressed: a course of conduct which, under the particular circumstances, discloses a reckless indifference to consequences without the exertion of any substantial effort to avoid them. *Dame v. Estes*, 233 Miss. 315, 318, 101 So. 2d 644 (1958). Moreover, punitive conduct does not need to be directed at a particular Plaintiff because the proper focus is whether the defendant intended to do the act that caused harm to come to a plaintiff. *Turner v. City of Ruleville*, 735 So. 2d 226, 230 (Miss. 1999) (reversing decision not to send punitive damages to the jury after an officer allowed a drunk driver to continue to drive before causing injury).

Plaintiff has submitted evidence that Defendants intentionally withheld from treating

physicians like Dr. DeVun the risks of the exact injury Mr. Nelson suffered. SOF 20, 22 -29, 33. Bard deliberately scripted a false safety story around its new filter knowing physicians were actively implanting these devices into the largest vein in their patients —the highway to the heart and lungs— with aggressive marketing techniques. SOF 22-23, 33. Bard stopped selling the Recovery filter in order to investigate the fractures and deaths but did not tell physicians who continued implanting the filters. SOF 20. After Bard lifted this internal hold on Recovery sales, it was implanted in Mr. Nelson knowing it had a fracture rate ten times higher than that of other filters on the market and it was measurably less safe than their own SNF filter. SOF 24-27. Defendants' April 2004 Crisis Communication Plan was developed with a public relations firm to intentionally hide the "problematic" comparisons between the Recovery and other, safer filters, as well as prevent exposure of the problems to the media. SOF21-22. Bard's employees not only delivered scripted messages to portray that Recovery complication rates were on par with other filters in an attempt to mix in well with its safer competitors, it actively promoted the Recovery as better than its competitors; a "marked improvement over currently available devices." SOF 27-28. Unfortunately, this was Bard's plan all along— that its "documented negative clinical experiences and no solid clinical history could be overcome with "aggressive marketing." SOF 33. Bard shared none of this information with the public and Dr. DeVun despite concerns of how desperate a situation they were in with the failures leading the marketing and sales managers to reflect on the situation as one needing to be held together with "scotch tape, smoke, mirrors, and crying." SOF 23. Bard was not a passive player with the ability to watch out for negligence or wrongdoing like the police officer who let a drunken driver continue to drive after pulling him over— behavior deemed grossly negligent. See *Turner* 735 So. 2d at 230. Bard actively withheld the danger by intentionally marketing aggressively around it, putting filters on the shelves at hospitals like drunk drivers on the roads, taking a chance that no one would get hurt. Bard betrayed doctors like Dr. DeVun caring for his patient. SOF 96. Had Dr. DeVun seen the safety information Bard withheld from him, he would not have used the filter. This conduct, similar to the conduct in *Turner,* is grossly negligent because Bard intentionally engaged in the exact activity without regard for

patient safety and actively downplayed the risk of injury. SOF 23.

In Georgia, where the punitive damages standard is comparable to Mississippi, a jury found punitive conduct with the next generation Recovery filter (G2); a ruling upheld on appeal. *Booker*, 969 F.3d 1067, 1077 (9th Cir. 2020) (internal quotations omitted). In *Booker* the evidence supported a finding that "despite knowing that G2 filters (predicated on the Recovery filter) placed patients at a greater risk of harm than other available filters, Bard chose not to warn physicians and instead downplayed the risk." The same conduct is present here, and yet another patient harmed. Plaintiff respectively requests that Defendants' Motion for Summary Judgment be denied in their request to strike punitive damages.

CONCLUSION

WHEREFORE, based on the foregoing, Plaintiff respectfully requests that this Court deny Defendants' Motion for Summary Judgment, on all claims except manufacturing defect, which Plaintiff withdraws, and grant the Plaintiff further relief to amend his complaint to comport with MPLA and the Mississippi Consumer Protection Act if the Court deems it necessary notwithstanding Plaintiff's compliance with the MDL orders regarding pleadings.

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Respectfully submitted,

/s/ Mark S. O'Connor (pro hac vice)

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that foregoing was electronically filed with the Court and that counsel of record, who are deemed to have consented to electronic service in the above-referenced case, are being served on April 19, 2021with a copy of the foregoing document via the Court's CM/ECF System.

/s/ Jessica Gallentine